REMARKS

The Official Action consisted of a restriction requirement and an election of species requirement. The follow remarks are believed to be fully responsive to the Official Action.

Restriction requirement

In accordance with 37 CFR 1.499 the applicant provisionally elects Group I, i.e. claims 44-69, 73 and 74 drawn to a vaccine composition. This election of the invention is made with traverse.

The reasons for traverse follow:

The Official Action refers to PCT Rule 13.1 when arguing that the claims 44-74 currently on file relate to two inventions.

PCT Rule 13.1 states that the international application can relate to a group of inventions so linked as to form a single general inventive concept. According to PCT Rule 13.2 this requirement of unity is fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

There is such a technical relationship among claims 44, 63, 69 and 70. The technical relationship is based on the special technical features of the nucleotide vaccine composition, i.e. being a mixture of nucleotide sequence encoding an antigen and

APCs modified for expression of at least one of an immune response modulating molecule and a cell-survival modulating molecule.

The Official Action continues by discussing that PCT Rule 13 permits unity for the following combination: a product, a *first* process of making the product and a *first* method of using the product.

Detailed information relating to the interpretation of PCT Rule 13 and unity of invention is found in Annex B of the Administrative Instructions. In those Administrative Instructions it is clear that unity of invention is present for a combination of claims of different categories having, in addition to, an independent claim for a given product (corresponds to claims 44, 73) also an independent claim for a process specially adapted for the manufacture of the said product (corresponds to claim 63), and an independent claim for use of the said product (corresponds to claims 69, 70).

There is no disclosure in Annex B of the Administrative Instructions stating that unity is permitted only for the combination of a product, a *first* process of making the product and a *first* method of using the product.

Thus, this interpretation of only permitting a single method of use has been made in the Official Action without any support from the Administrative Instructions.

Moreover, Part 1b of the Annex B of the Administrative Instructions specifies that that special technical features are those features that define the contribution which each of the inventions, considered as a whole, makes over the prior art. In other words, a determination of lack of unit is art-based and requires the citation of a publication showing the "special technical feature".

Thus, absent any showing that the special technical feature is present in a prior art reference, no determination of lack of unity can properly be made. As the Official Action fails to provide such a citation, the lack of unity requirement is improper as a matter of law.

Indeed, in applying this same legal standard discussed above with similar claims, the International Searching Authority did not determine the unity of invention as lacking. The Official Action fails to explain why a different legal conclusion was reached.

Therefore, Applicant respectfully submits that all the claims 44-74 currently on file meet the unity requirement and are so linked as to form a single general inventive concept under PCT Rule 13.

Election of species

The Official Action has identified four species:

A) antigen presenting cells, recited in claim 53,

B) immune response modulating molecules, recited in claims 54, 55 and 58-61,

C) cell-survival modulating molecule, recited in claim 56, and

D) vector, recited in claim 57.

Regarding species A, Applicant elects the species “natural-interferon producing cells”.

Regarding species B, Applicant disagrees that claims 54, 55 and 58-61 relate to an immune response modulating molecule. Claims 54 and 55 disclose different species of the immune response modulating molecule that is expressed by the modified APCs defined in claim 44. However, claims 58-61 disclose that the nucleotide vaccine composition comprises, in addition to the antigen-encoding nucleotide sequence and the modified APCs, an immune response modulating sequence (claims 58, 60), which is preferably an unmethylated CpG sequence (claims 59, 61). Thus, claims 54, 55 relate to the immune response modulating molecule defined in claim 44 whereas claims 58-61 relate to an immune response modulating nucleotide sequence, which is a different species as compared to the immune response modulating molecule.

Consequently, species B relating to immune response modulating molecules is recited in claims 54, 55. The Applicant has elected the species “CD40 ligand”.

Regarding species C, the Applicant elects the species "apoptosis inducing gene".

Regarding species D, the Applicant elects the species "plasmid".

Conclusion

In view of the foregoing remarks, a favorable action on the merits on all claims, in their full scope, is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/

Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/fb